

Billie Schwarz  
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Ontario, CA 91764

March 17, 1999

Dockets Management Branch (HFA-305)  
Food & Drug Admin. Docket # 98N-1265  
5630 Fishers Lane, Room 1061  
Rockville MD 20852

Dear FDA:

I feel that the way you have written the restrictions, limiting the sales to **ONLY 5%** for out-of-state, or the compounding pharmacies will be out of compliance, in the Memorandum of Understanding, as published by your office on January 21, 1999, **THAT YOU ARE DISCRIMINATING AGAINST THE COMPOUNDING PHARMACIES AND WE PATIENTS AND OUR DOCTORS WHO USE THEM!**

**THE FDA MODERNIZATION ACT OF 1997 DOESN'T SAY WHAT AN INORDINATE AMOUNT IS, AND UNFORTUNATELY, THE LEGISLATORS HAVE LEFT THAT UP TO YOU TO DECIDE. THE BILL DOES NOT SAY 5%, OR 20%, WHICH IS THE CARROT THAT YOU ARE HOLDING OUT TO THE STATES IF THEY SIGN THE MOU, AND IF THEY DON'T SIGN THE MOU, THEN YOU ARE ONLY PROPOSING 5%!!! THAT WAS NOT THE LEGISLATIVE INTENT OF THAT BILL!**

My daughters and I have been greatly relieved of PMS, depression, and insomnia from our compounded natural hormones. Please do not restrict out-of-state compounding pharmacies from selling them. As long as we have a prescription and therefore, are following the good practice of pharmacies, then you need to let us have access and freedom of choice. The states already regulate the practice of pharmacies, and therefore, I do not believe that you are following the legislative intent of the FDA Modernization Act of 1997.

Physicians rely on the drug companies to tell them what is available. **Compounding pharmacies are already restricted. They cannot advertise nor solicit.** Compounding pharmacies have been around before the pill dispensing pharmacists. Now you are telling them that they can not do their job, and in order to have an exemption from the NDA, and in order to keep compounding, they can't ship it to other states! That is not right!

Our family would like to recommend that you do not impose these severe (5%), restrictions on their trade. I doubt very seriously if the compounding pharmacies can make up a very big batch anyway, as they can't have it sitting around. You are very mistaken if you think that enough gynecologists know anything about natural hormones. Most of them do not even know anything about micronized progesterone. They only know what the big drug companies tell them, (The ones who fund the medical schools that they go to.)

Sincerely,

*Billie Schwarz*

*cc. Cong. Brown, Sen. Boxer + Feinstein*

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